

## **REMARKS/ARGUMENTS**

### **Amendment to the Claims**

Claims 1-15 and 17-21 are in the application. Claims 1, 4, 10, 13, 17 and 20 are amended. Claims 2, 11 and 21 are canceled. New Claim 22 is added.

Claim 1 is amended to provide that size of the injection needle effects a painless insertion of the needle (support at para. [0084]), and to insert the features of now canceled Claim 2, which provides for a manually-powered spring that exerts pressure upon the injectable liquid composition within the retained reservoir to inject the injectable liquid at a substantially constant volumetric flow rate of about 0.5  $\mu\text{L/s}$  to about 20  $\mu\text{L/s}$  from the reservoir through the needle, which effects a painless injection.

Claim 4 is amended to better present the claim.

Claim 10 is amended to provide that size of the injection needle effects a painless insertion of the needle (support at para. [0084]), and to insert the features of now canceled Claim 11, which provides for a manually-powered spring that exerts pressure upon the injectable liquid composition within the retained reservoir to inject the injectable liquid at a substantially constant volumetric flow rate of about 0.5  $\mu\text{L/s}$  to about 20  $\mu\text{L/s}$  from the reservoir through the needle, which effects a painless injection.

Claim 13 is amended to better present the claim.

Claim 17 is amended to change claim dependency.

Claim 20 is amended to better present the claim.

New Claim 22 is identical to original Claim 16 as filed.

No new claims fees are believed due, and all claim amendments are fully supported by the specification as originally filed.

### **Interview**

Following the mailing of the Advisory Action on October 20, 2009, Applicants discussed the rejection in an interview on November 5, 2009 with Patent Examiner Nathan Price and Supervisory Patent Examiner Nicholas Lucchesi, for which Applicants are very grateful.

During the interview, Applicants' attorney discussed the injection means and the failure of the prior art references to teach an injection rate that can effect a painless intermuscular

injection, specifically at a rate of about 0.5  $\mu\text{L/s}$  to about 20  $\mu\text{L/s}$ , as now provided in Claims 1 and 10. The Examiners mentioned that the Office might agree, and expressed a willingness to review the matter after final upon filing of this response.

Also during the interview, Applicants' attorney discussed the features of the retracting means, which are found in claims 4 and 17, as distinguishing over the features of the reference Miskinyar, which mentions the phrase "retracting means" but does not in fact disclose or suggest an element that meets the requirement of the retracting means of Applicants' claims. The Examiners mentioned that the Office might agree.

Applicants' attorney also noted that an assertion in the Advisory Action that "(o)ne of ordinary skill in the art at the time of the invention was made would understand that pain threshold would not only vary from person to person and from injection location to injection location, but also between species", suggests facts that are not well known or are not of common knowledge in the art capable of instant and unquestionable demonstration as being well known, and therefore require some reference in support.

#### **Rejections under 35 USC §103(a)**

##### **A. Claims 1, 2, 10, 11 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miskinyar (US 5527287) in view of Woehr et al. (US 20030144627)**

Applicants respectfully request reconsideration and withdrawal of the rejection.

As noted above, the prior art references fail to teach, inherently or expressly, or to suggest, an injection rate that can effect a painless intermuscular injection, specifically at a rate of about 0.5  $\mu\text{L/s}$  to about 20  $\mu\text{L/s}$ , as now provided in amended Claims 1 and 10.

Also noted above, an assertion in the Advisory Action that "(o)ne of ordinary skill in the art at the time of the invention was made would understand that pain threshold would not only vary from person to person and from injection location to injection location, but also between species", suggests facts that are not well known or are not of common knowledge in the art capable of instant and unquestionable demonstration as being well known, and therefore require some reference in support.

Applicants have asserted in the last response mailed April 27, 2009 that Miskinyar fails to disclose a manually-powered injection device, as such would be understood by a person of

ordinary skill given the broadest reasonable interpretation of Applicants' specification. The body the Claim 1 requires that the needle is configured for axial movement manually between a first position wherein the injection end is within the housing and a second position for intramuscular insertion of the injection end, and the manually-powered spring, such that the preamble recitation of "manually-powered" in the preamble should also be considered for its patentable weight. Quite the contrary, the device of Miskinyar requires a pre-charged syringe that uses an actuator button to release the pre-charged needle for injection.

For these reasons, Applicants request reconsideration and withdrawal of the rejection.

**B. Claims 3-8, 12-15 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miskinyar in view of Woehr et al., and further in view of McWethy et al. (US 7004929).**

Applicants respectfully request reconsideration and withdrawal of the rejection.

Applicants assert that the claimed feature of the retracting means, which are found in claims 4 and 17, is distinguishing over the features of the reference Miskinyar, which mentions the phrase "retracting means" but does not in fact disclose or suggest an element that meets the requirement of the retracting means of Applicants' claims.

**C. Claims 9 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miskinyar in view of Woehr et al., and further in view of Flaherty (US 6749587).**

Applicants respectfully request reconsideration and withdrawal of the rejection, in view of the claim amendments and arguments with respect to claims from which the rejected claim depend.

**D. Claims 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miskinyar in view of Woehr et al. and McWethy, and further in view of Landau (US 6264629).**

Applicants respectfully request reconsideration and withdrawal of the rejection, in view of the claim amendments and arguments with respect to claims from which the rejected claim depend.

**Prosecution of Related Patent Applications**

Applicants wish to bring to the Examiner's attention the examination status of related patent applications commonly assigned to the assignee of the instant application:

- i) **US Appln. 10/605,187** (Attorney docket CHM-005M), is allowed.
- ii) **US Appln. 10/597,997** (Attorney docket CHM-022M), an RCE was filed on Nov. 10, 2009.

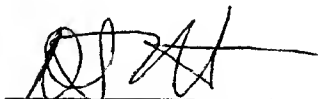
**Conclusion**

Applicants believe a complete response to the final office action has been provided, which places all claims into condition for allowance. The Examiner is requested to notify Applicants' attorney at the phone number shown below, once the Office has determined that it intends to allow, or not allow, the present application.

Respectfully submitted,

For: Eric James WALL et al.

By:



Daniel F. Nesbitt  
Attorney for Applicants  
Registration No. 33,746  
Phone: (513) 229-0383  
Customer Number 38155

November 24, 2009